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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,833	01/11/2002	Jim Wells	SUNESIS.2DV1C1	3663

20995 7590 11/19/2002

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EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary <i>File Copy</i>	Application No. 10/043,833	Applicant(s) WELLS ET AL.	
	Examiner Jon D Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 40-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 40-56, drawn to a process comprising “(a) screening a library of small organic compounds with a target protein-ligand conjugate ... and (b) identifying a small organic compound”, classified variously in class 435, DIG 18; class 435, subclass 7.1.
 - II. Claims 57-62, drawn to a method for “identifying a small organic compound that forms a covalent bond with a chemically reactive group on a target biological molecule”, classified variously in class 435, DIG 17; class 435, DIG 18; class 435, DIG 19; class 435, subclass 6.
2. The inventions are distinct, each from the other because of the following reasons:

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3. Groups I and II represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group I employs a target “protein”-ligand whereas the method of Group II employs a target “biological molecule”, which would not necessarily include a “protein” conjugate. For example, the “target biological molecule” could include a “nucleic acid” or “polysaccharides”, which would lead to different searches in different classifications e.g., class 435, DIG 18 for the “nucleic acid” or class 435, DIG 17 for the “polysaccharide” as opposed to class 435 DIG 15 for the “proteins” in Group I, which would be unduly burdensome. Therefore, Groups I and II have different issues regarding patentability and enablement and represent patentably distinct subject matter.

4. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

5. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-II. Election is required as follows.

6. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 40 is generic.

Subgroup 1: Species of first covalent bond (see claim 40)

Applicant must elect, for the purposes of search, a *single species* of covalent bond e.g., disulfide bond. Furthermore, applicant *must* indicate which claims read on the elected species.

Subgroup 2: Species of first reactive functionality (see claim 40)

Applicant must elect, for the purposes of search, a *single species* of first reactive functionality e.g., thiol. Furthermore, applicant *must* indicate which claims read on the elected species.

Subgroup 3: Species of second reactive functionality (see claim 40)

Applicant must elect, for the purposes of search, a *single species* of second reactive functionality e.g., thiol. Furthermore, applicant *must* indicate which claims read on the elected species.

Subgroup 4: Species of second covalent bond (see claim 40)

Applicant must elect, for the purposes of search, a *single species* of second covalent bond e.g., disulfide bond. Furthermore, applicant *must* indicate which claims read on the elected species.

Subgroup 5: Species of chemically reactive group (see claim 44)

Applicant must elect, for the purposes of search, a *single species* of chemically reactive group e.g., thiol. Furthermore, applicant *must* indicate which claims read on the elected species.

Subgroup 6: Species of member of the library of small organic compounds (see claims 45-46)

Applicant must elect, for the purposes of search, a *single species* of member of the library of small organic compounds e.g., thiols. Furthermore, applicant *must* indicate which claims read on the elected species.

Subgroup 7: Species of identifying step (see claims 47-55)

Applicant must elect, for the purposes of search, a *single species* of identifying step e.g., mass spectrometry, NMR, X-ray crystallography. Furthermore, applicant *must* indicate which claims read on the elected species.

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If applicant elects “mass spectrometry” as the identifying step, applicant must further elect an “agent” from claim 52 e.g., sodium borohydride.

Subgroup 8: Species of target protein (see claim 56)

Applicant must elect, for the purposes of search, a single species of target protein e.g., TNF. Furthermore, applicant must indicate which claims read on the elected species. Please note: electing “enzymes” for example would not qualify as a “single” species election because enzymes would encompass more than one species, “proteases”, “kinases”, etc i.e., there must be an election of only one target protein.

7. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 57 is generic.

Subgroup 1: Species of first reactive functionality (see claim 58)

Applicant must elect, for the purposes of search, a single species of first reactive functionality on the TBM e.g., thiol. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 2: Species of second reactive functionality (see claim 58)

Applicant must elect, for the purposes of search, a single species of second reactive functionality e.g., thiol. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 3: Species of covalent bond (see claims 57, 59-60)

Applicant must elect, for the purposes of search, a single species of covalent bond e.g., thioether. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 4: Species of chemically reactive group (see claim 61)

Applicant must elect, for the purposes of search, a single species of chemically reactive group e.g., activated thiol. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 5: Species of member of the library of small organic compounds (see claim 62)

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Applicant must elect, for the purposes of search, a single species of member of the library of small organic compounds e.g., thiol. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 6: Species of identifying step (see claim 57)

Applicant must elect, for the purposes of search, a single species of identifying step e.g., mass spectrometry, NMR, X-ray crystallography. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 7: Species of target biological molecule (see claim 57)

Applicant must elect, for the purposes of search, a single species of target biological molecule. Furthermore, applicant must indicate which claims read on the elected species.

8. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

14. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an “action on the merits” for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

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Jon D. Epperson, Ph.D.

November 16, 2002

BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Bennett Celsa', written in a cursive style.